K072258

**510(k) Summary of Safety and Effectiveness**
**As required by 807.92**
**for BI-RADS Companion**
**Prepared on August 7, 2007**
**Revised October 31, 2007, January 29, 2008, April 18, 2008, May 16, 2008**

MAY 16 2008

Submitted by: Almen Laboratories, Inc.
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Vista, CA 92084

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Contact Person: Roger H. Schneider
6319 Massachusetts Avenue
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Tel. 301-229-8442 Fax: 301-229-8485

Device Trade Name: **BI-RADS Companion**

Common Name: Medical Image Processing System

Classification: Class II, 21 CFR 892.2050 PACS

Predicate Device: **B-CAD System, Version 1.0 (K050846)**

Manufactured by: MEDIPATTERN CORPORATION
2300 Sheppard Avenue West
Suite 204, Toronto, Ontario M9M 3 A4

**Indications for Use**

BI-RADS Companion™ ("BRC") is a computer–aided image viewing and report generating tool designed to assist radiologists in the analysis of ultrasound images of breast masses by making the ACR "BI-RADS Classification Form and Lexicon®" ("ABCFL") available in electronic format. The user can view any selected image from a case and segment the lesion from the background by applying a user selected threshold or outlining the lesion manually with a cursor.

The user can annotate, tag, measure, and record selected views. Under user control and review, the software electronically assembles reports from inputs selected by the user from the ultrasound ABCFL during the image interpretation process. The assembled report complies with the ABCFL for ultrasound. The output may be viewed and sent to electronic storage media, or standard film or paper printers or other document manipulation programs such as Adobe or Microsoft.

When used by a skilled radiologist, this device provides information that may be useful in image interpretation. Patient management decisions should not be based solely on forms generated by BRC.

The ultrasound images displayed by BRC must not be used for primary diagnostic interpretation.

## Description of the Device:

BI-RADS Companion™ ("BRC") is a computer–aided image viewing and report generating tool designed to assist radiologists in the analysis of ultrasound images of breast masses by making the ACR "BI-RADS Classification Form and Lexicon®" ("ABCFL") available in electronic format. The user can view any selected image from a case and segment the lesion from the background by applying a user selected threshold or outlining the lesion manually with a cursor.

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Substantial Equivalence to Predicate Device: **BI-RADS Companion** is substantially equivalent to: **B-CAD System, Version 1.0. (K050846)**

The following table is a comparison of the functions of the device.

| | Function | BI-RADS Companion, Version 1.0 (K072258) | B-CAD System, Version 1.0. (K050846) |
|---|---|---|---|
| 1 | Intended as aide to radiologists' reviewing of images of masses in the human female breast | yes | yes |
| 3 | Windows 2000/XP based DICOM File Set Reader (FSR) compatible platform may be installed on a PC, Notebook or Workstation with HL7 compatibility | yes | yes |
| 4 | User interface designed to follow typical clinical workflow patterns to process, review and analyze digital images | yes | yes |
| 5 | User may annotate, tag, calibrate, measure and automatically record selected views | yes | yes |
| 6 | Automatically generates reports with user annotations during image analysis process. Allows saving custom annotations of images of confirmed cases to be used for future reference and education | yes | yes |
| 7 | Annotations is based on ACR ABCFL Breast Imaging Atlas | yes | yes |
| 8 | Report format supports compliance with ACR ABCFL | yes | yes |
| 9 | Outputs may be viewed and sent to standard film or paper printers or sent electronically to intranet web server or other HL7 compliant media format | yes | yes |
| 10 | Display multiple and full study views | yes | yes |
| 11 | Radiologist's BI-RADS assessment based on visual impressions of the user ABCFL | yes | yes |

The intended use, design, function, and performance characteristics for **BRC** are substantially equivalent to the predicate device listed above. It is the opinion of Almen Laboratories, Inc., that **BRC** raises no new issues of safety and effectiveness compared to these predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ALMEN LABORATORIES, Inc.
% Mr. Roger Schneider
Consultant
Medical & Radiation Technology
6319 Massachusetts Avenue
BETHESDA MD 20816

MAY 16 2008

Re: K072258
Trade/Device Name: BI-RADS Companion
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 20, 2008
Received: March 21, 2008

Dear Mr. Schneider:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

| | | |
|---|---|---|
| 21 CFR 876.xxxx | (Gastroenterology/Renal/Urology) | 240-276-0115 |
| 21 CFR 884.xxxx | (Obstetrics/Gynecology) | 240-276-0115 |
| 21 CFR 892.xxxx | (Radiology) | 240-276-0120 |
| Other | | 240-276-0100 |

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K072258

Device Name: BI-RADS Companion

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Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072258